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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2017-0015]

Bayer CropScience LP.; Availability of Draft Environmental Assessment, Plant Pest Risk Similarity Assessment, Preliminary Finding of No Significant Impact, and Preliminary Decision for an Extension of a Determination of Nonregulated Status of Canola Genetically Engineered for Male Sterility and Glufosinate-Ammonium Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has reached a preliminary decision to extend our determination of nonregulated status of InVigor® MS8 canola (hereinafter MS8 canola) to Bayer's canola event MS11 in response to a request from Bayer CropScience LP. MS11 canola has been genetically engineered for male sterility and resistance to the herbicide glufosinate-ammonium using the same mechanism of action as MS8 canola. We are making available for public comment our draft environmental assessment, preliminary regulatory determination, preliminary finding of no significant impact, and plant pest risk similarity assessment for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to
<http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0015>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2017-0015, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The Bayer CropScience LP. extension request, our draft environmental assessment, plant pest risk similarity assessment, our preliminary finding of no significant impact, our preliminary determination, and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0015> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents and any comments we received regarding our determination of nonregulated status of the antecedent organism, MS8 canola, may be inspected in our reading room. Supporting documents may also be found on the APHIS Web site for MS11 canola (the organism under evaluation) under APHIS Petition Number 16-235-01p.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Document Control Officer/Team Leader, Policy Coordination Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147 Riverdale, MD 20737-1236; (301) 851-3954, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms (GE) and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

On March 31, 1999,¹ APHIS announced its determination of nonregulated status of MS8 canola (Brassica napus L.), which was genetically engineered for male sterility and resistance to the herbicide glufosinate-ammonium. APHIS has received a request for an extension of that determination of nonregulated status of MS8 canola to canola designated as canola event MS11 (APHIS Petition Number 16-235-01p) from Bayer CropScience LP. (Bayer) of Research Triangle Park, NC. MS11 canola expresses male sterility and resistance to the herbicide

¹ https://www.federalregister.gov/documents/1999/03/31/99-7803/agrevo-usa-co-availability-of-determination-of-nonregulated-status-for-canola-genetically-engineered?utm_content=next&utm_medium=PrevNext&utm_source=Article.

glufosinate-ammonium. In its request, Bayer stated that this canola is similar to the antecedent organism MS8 canola and, based on the similarity to the antecedent organism, is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the extension request, MS11 canola was developed using the gene cassette pTCO113 containing the same genetic events used to transform MS8 canola (gene cassette pTHW107) with male sterility and resistance to glufosinate-ammonium. Based on the information in the request, we have concluded that MS11 canola is similar to MS8 canola. MS11 canola is currently regulated under 7 CFR part 340.

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS evaluates the plant pest risk of the article. In section 403 of the PPA, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS has prepared a plant pest risk similarity assessment (PPRSA) to compare MS11 canola to the antecedent. As described in the PPRSA, the proteins expressed in MS11 canola are similar to those expressed in MS8 canola, and APHIS has concluded that the proteins expressed in MS8 canola are unlikely to pose a plant health risk. Therefore, based on the similarity between MS8 canola and MS11 canola as described in the PPRSA, APHIS has concluded that MS11 canola is no more likely to pose a plant pest risk than MS8 canola.

APHIS has also prepared a draft environmental assessment (EA) in which it presents two alternatives based on its analysis of data submitted by Bayer, a review of other scientific data,

and field tests conducted under APHIS oversight. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of MS11 canola and it would continue to be a regulated article, or (2) make a determination of nonregulated status for MS11 canola.

Based on the similarity of MS11 canola to MS8 canola, APHIS has also prepared a preliminary finding of no significant impact (FONSI) for MS11 canola. The draft EA and the FONSI were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

APHIS has analyzed information submitted by Bayer, references provided in the extension request, peer-reviewed publications, and supporting documentation prepared for the antecedent organism. Based on APHIS' analysis of this information and the similarity of MS11 canola to the antecedent organism MS8 canola, APHIS has determined that MS11 canola is unlikely to pose a plant pest risk. We have therefore reached a preliminary decision to approve the request to extend the determination of nonregulated status of MS8 canola to MS11 canola, whereby MS11 canola would no longer be subject to our regulations governing the introduction of certain genetically engineered organisms.

Paragraph (e) of § 340.6 provides that APHIS will publish a notice in the Federal Register announcing all preliminary decisions to extend determinations of nonregulated status for 30 days before the decisions become final and effective. In accordance with § 340.6(e) of the

regulations, we are publishing this notice to inform the public of our preliminary decision to extend the determination of nonregulated status of MS8 canola to MS11 canola.

APHIS will accept written comments on the draft EA and preliminary FONSI regarding a determination of nonregulated status of MS11 canola for a period of 30 days from the date this notice is published in the Federal Register. The draft EA and preliminary FONSI, as well as the extension request, PPRSA, and our preliminary determination for MS11 canola, are available for public review as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above. Copies of these documents may also be obtained by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments will be available for public review. After reviewing and evaluating the comments, APHIS will furnish a response to the petitioner regarding our final regulatory determination. APHIS will also publish a notice in the Federal Register announcing the regulatory status of MS11 canola and the availability of APHIS' written environmental decision and regulatory determination.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 6th day of April 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

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